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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,047	02/17/2004	Steven P. Gygi	57559 (70207)	8390

7590 05/05/2006

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EXAMINER	
BULL, CHRISTOPHER	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,047	GYGI ET AL.	
	Examiner	Art Unit	
	Christopher Bull	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5 and 23-24, drawn to a method of making an isotopically labeled peptide internal standard, classified in class 436, subclass 15.

II. Claims 6-22 and 25, drawn to a method of determining the presence and/or quantity of a target polypeptide in a mixture, classified in class 436, subclass 173.

III. Claims26-40, drawn to one or more isotopically labeled peptide internal standards, classified in class 436, subclass 86.

IV. Claims 41-46, drawn to kits comprising isotopically labeled peptide internal standards and software for accessing the information therein, classified in class 435, subclass 975.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)). The product, a peptide internal standard as made by the methods of Invention I as instantly claimed, while not claimed in the instant application, still would not be allowable over Barr et al. (1996 Clinical Chemistry 42(10), 1676-1682,

particularly page 1678). Barr et al. identified and sequenced tryptic peptides of apolipoprotein A-1, synthesized corresponding labeled peptides and recorded their peptide signatures (lower right page 1678 - *identification of peptides & next paragraph*).

Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the inventions of Invention III, i.e., the panels of labeled peptide internal standards, could be made by isotopically labeling the growth medium of the polypeptide(s) source(s) with a stable isotope(s), purifying the protein(s) of interest, cleaving with a selected protease, purifying the peptides and recording the peptide diagnostic signature of each. Such a process would skip steps a) to d) in Claim 1 and meet all limitations of Claims 1-5 and the requirement for the peptide internal standards of Invention III.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the invention of Invention IV, the various kits, could be made with peptide internal standards made as just discussed in the preceding paragraph, and the computer files, etc., are not the direct product of the method of Invention I.

Inventions II and III-IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the two products, the panels or the kits, could be used in NMR studies of the conformation of the peptides in solutions, wherein isotopic substitution is often advantageous.

Inventions III and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination as claimed in the kit allows a single or unmodified peptide internal standard to be used, whereas the panels recite either multiple peptide internal standards or one containing a modification site. The subcombination has separate utility such as the NMR conformation studies of the previous paragraph, which do not require the computer files of the kit.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The inventions above are distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require

independent searches (as indicated by the different classification). The search for each of the above inventions is not co-extensive particularly with regard to the literature search. For example, searching the chemical synthesis literature for methods of making peptide internal standards would not reveal many instances of uses of such standards in the biochemical literature. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. For example, anticipation of either method might not anticipate the panels. Finally, the consideration for patentability is different in each case. For example, the computer methods recited in the kits are not a part of the methods or panels. Thus, it would be an undue burden to examine all of the above inventions in one application.

Accordingly, restriction for examination purposes as indicated is proper.

Election of Species

This application further contains claims directed to the following patentably distinct types of species: Type I – Mixtures of Polypeptides as in Claim 11; Type II – Amino Acid Residue Modifications as in Claim 27; Type III – Molecular Pathways as in Claim 31; Type IV – Diseases as in Claims 35-39. These types of species are independent or distinct because, while each type is defined by a function or definition, the species within each type do not share a common structure or property that makes the other species of that Type predictable. The four Types of species are listed below.

Type I – Mixtures of Polypeptides:

a crude fermenter solution; a cell-free culture fluid; a cell or tissue extract; a blood sample; a plasma sample; a lymph sample; a cell or tissue lysates; a mixture of at

least about 100 different polypeptides; a mixture comprising substantially the entire complement of proteins in a cell or tissue.

Type II – Amino Acid Residue Modifications:

phosphorylated; glycosylated; ubiquitinated; ribosylated; acetylated; farnesylated.

Type III – Molecular Pathways:

JAK; MAPK; cell cycle; G-protein coupled.

Type IV – Diseases:

neurodegenerative; cancer specific antigens; respiratory; autoimmune; infectious.

Because these species are distinct within each Type for the reasons given above and the species require a different fields of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper. Separate searches are required for each species of each type. Each has synonyms and literature distinct from the others, as can be seen in the above lists of species. Thus, it would be an undue burden to examine all of the above species in one application.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of an invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each Type for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 6, 11 26, 27, 30, 31, 33 and 35-39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of species to be examined even though the requirement be

traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species.

The election of species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other species.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Bull whose telephone number is (571) 272-1327. The examiner can normally be reached on 7:30-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/

Christopher Bull
Patent Examiner
Art Unit 1655

cb

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